IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF MISSISSIPPI
OXFORD DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. DELTA PHARMA, INC., a corporation, and TOMMY T. SIMPSON and CHARLES MICHAEL HARRISON, individuals, Defendants.	)	Civil Action No. 3:18-cv-127-NBB-JMV **CONSENT DECREE OF PERMANENT INJUNCTION**

Plaintiff, the United States of America, by its undersigned attorneys, having filed a Complaint for Permanent Injunction against Defendants, Delta Pharma, Inc. ("Delta Pharma"), a corporation, and Tommy T. Simpson and Charles Michael Harrison, individuals (collectively, "Defendants"), and Defendants having appeared and having consented to the entry of this Consent Decree of Permanent Injunction ("Decree") without contest, without admitting or denying the allegations in the Complaint, and before any testimony has been taken, and the United States of America having consented to this Decree;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter and all parties to this action under 28 U.S.C. §§ 1331 and 1345, 21 U.S.C. § 332, and its inherent equitable authority.

2. The Complaint for Permanent Injunction states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–399i (the "Act").

3. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(a), by introducing or causing to be introduced, or delivering or causing to be delivered for introduction,

into interstate commerce, articles of drug that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A), in that the drugs have been prepared, packed, or held under insanitary conditions whereby they may have been contaminated with filth or whereby they may have been rendered injurious to health.

4. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(a), by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce, articles of drug that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), in that the methods used in, or the facilities or controls used for, their manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with, current good manufacturing practice to assure that such drugs meet the requirements of the Act as to safety and have the identity and strength, and meet the quality and purity characteristics, which they purport or are represented to possess.

5. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(a), by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce, articles of drugs that are misbranded within the meaning of 21 U.S.C. § 352(f)(1), in that their labeling does not bear adequate directions for use.

6. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(k), by causing articles of drug to become adulterated within the meaning of 21 U.S.C. §§ 351(a)(2)(A) and 351(a)(2)(B), and to become misbranded within the meaning of 21 U.S.C. § 352(f)(1), while the drugs are held for sale after shipment of one or more of their components in interstate commerce.

7. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(d), by introducing or causing to be introduced, or delivering or causing to be delivered for introduction,

into interstate commerce, new drugs, as defined by 21 U.S.C. § 321(p), that are neither approved pursuant to 21 U.S.C. § 355, nor exempt from approval.

8. For the purposes of this Decree, the following definitions shall apply:

A. "Bulk drug substance" shall refer to bulk drug substance as defined in 21 C.F.R. § 207.3 or any successor regulation. Defendants may use bulk drug substances in compounding drugs at an outsourcing facility consistent with 21 U.S.C. § 353b(a)(2) and any applicable regulation, or guidance issued by FDA, or any successor regulation or guidance.

B. "CGMP" shall refer to the current good manufacturing practice requirements for drugs within the meaning of 21 U.S.C. § 351(a)(2)(B) and 21 C.F.R. Parts 210 and 211. In determining whether Defendants are compounding drugs at an outsourcing facility in compliance with CGMP, Defendants, their expert consultants, and FDA may consider any regulations and/or guidance that FDA has issued with respect to CGMP for outsourcing facilities;

C. "Compound" and "compounding" shall include the combining, admixing, mixing, diluting, pooling, reconstituting, or otherwise altering of a drug or bulk drug substance to create a drug;

D. "Days" shall refer to calendar days unless otherwise stated;

E. "Defendants' facility" shall refer to the facility located at 114 W. Mulberry Street, Ripley, Mississippi 38663, and any other location(s) (including any new locations) at or from which, at any time in the future, any Defendant, directly or indirectly, manufactures, holds, and/or distributes drugs, whether or not any Defendant has an ownership interest in the business;

F. "Distribution" and "distributing" shall mean to sell, trade, ship, or deliver and shall include, but not be limited to, delivery or shipment to a healthcare setting for administration and dispensing to a patient or to an agent of a patient;

G. "Drug" shall have the meaning given the term in 21 U.S.C. § 321(g)(1);

H. "Drug product" shall mean a finished dosage form (for example, tablet, capsule, or solution) that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients;

I. "FDA" shall mean the United States Food and Drug Administration;

J. The terms "manufacture," "manufactured," and "manufacturing" shall include manufacturing, compounding, processing, packing, repacking, and labeling drugs;

K. "New drug" shall have the meaning as set out in 21 U.S.C. § 321(p); and

L. "Sterile drug" shall have the meaning as set out in 21 U.S.C. § 353b(d)(5).

9. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including, but not limited to, Hauck Family Trust) who have received actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined, under 21 U.S.C. § 332(a) and the inherent equitable authority of this Court, from directly or indirectly manufacturing, holding, and/or distributing any drugs manufactured at and/or from Defendants' facility, unless and until:

A. Defendants ensure that the facilities, methods, and controls used to manufacture, hold, and/or distribute drugs are established, operated, and administered in conformity with this Decree, the Act, and its implementing regulations, and are adequate to prevent Defendants' drugs from becoming adulterated within the meaning of 21 U.S.C. §§ 351(a)(2)(A) and 351(a)(2)(B), unapproved new drugs within the meaning of 21 U.S.C. § 355, and/or misbranded within the meaning of 21 U.S.C. § 352(f)(1);

B. Defendants ensure that each and every drug that Defendants intend to manufacture, hold, and/or distribute at or from their facility satisfies all of the provisions of 21 U.S.C. § 353b, including but not limited to:

(1) Drug labeling at 21 U.S.C. § 353b(a)(10);

(2) Facility registration at 21 U.S.C. § 353b(b)(1);

(3) Use of bulk drug substances at 21 U.S.C. § 353b(a)(2);

(4) Drug reporting at 21 U.S.C. § 353b(b)(2); and

(5) Adverse event reporting at 21 U.S.C. § 353b(b)(5);

C. Defendants retain, at Defendants' expense, an independent person or persons (the "CGMP Expert") who: (1) is without any personal or financial ties (other than a retention agreement to satisfy the requirements of this provision) to Defendants or their families; and (2) by reason of background, training, education, or experience, is qualified to conduct inspections to determine whether Defendants' facility, methods, and controls are established, operated, and administered in conformity with CGMP, to prevent Defendants from manufacturing, holding, and/or distributing drug products that are adulterated within the meaning of 21 U.S.C. §§ 351(a)(2)(A) and 351(a)(2)(B), unapproved new drugs within the meaning of 21 U.S.C. § 355, and/or misbranded within the meaning of 21 U.S.C. § 352(f)(1), and to recommend corrective actions. Defendants shall notify FDA in writing of the identity and qualifications of the CGMP Expert within ten (10) days after retaining any such CGMP Expert;

D. Defendants submit a protocol that identifies the work plan for the CGMP Expert and the methodology that shall be used by the CGMP Expert (the "Work Plan") to: (1) conduct inspection(s) of Defendants' facility as described in paragraph 9.E.; (2) ensure that Defendants implement all recommended corrective actions; and (3) ensure that Defendants'

procedures for manufacturing, holding, and/or distribution of drugs are adequate to prevent Defendants drug products from becoming adulterated within the meaning of 21 U.S.C. §§ 351(a)(2)(A) and 351(a)(2)(B) and/or misbranded within the meaning of 21 U.S.C. § 352(f)(1). Defendants shall not implement the Work Plan prior to receiving FDA's written approval, and in no circumstances, shall FDA's silence be construed as a substitute for written approval. FDA will review and provide a written response regarding the Work Plan as soon as practicable;

E. The CGMP Expert reviews all observations listed on Forms FDA-483 issued to Defendants since March 2004 and performs comprehensive inspection(s) of Defendants' facility and the methods and controls used to manufacture, hold, and/or distribute drugs to determine whether Defendants' facility, methods, and controls are, at a minimum, in conformity with CGMP and are adequate to prevent Defendants' drug products from becoming adulterated within the meaning of 21 U.S.C. §§ 351(a)(2)(A) and 351(a)(2)(B), unapproved new drugs within the meaning of 21 U.S.C. § 355, and/or misbranded within the meaning of 21 U.S.C. § 352(f)(1). The CGMP Expert shall evaluate, at a minimum, whether:

(1) Defendants have established and implemented an adequate written cleaning and disinfection program that they have shown through valid scientific evidence is effective for cleaning and disinfecting equipment and facilities used to manufacture drugs;

(2) Defendants have established and implemented an adequate environmental monitoring program to: (a) ensure that all sterile and/or aseptic operations are properly monitored (including surfaces and air quality); (b) include scientifically sound pre-established limits; and (c) ensure that Defendants identify, review, and address any results that exceed the pre-established limits and any adverse trends;

(3) Defendants have established and implemented adequate written procedures designed to prevent microbiological contamination of drug products purporting to be sterile including, but not limited to, media fill simulations and validation of all aseptic and sterilization processes;

(4) Defendants have established and implemented an adequate testing program designed to assess the stability characteristics of their drug products, including, but not limited to preservative content testing;

(5) Defendants have established and implemented written procedures to ensure that they: (a) thoroughly investigate any unexplained discrepancy or the failure of a batch of drug product, whether or not the batch has already been distributed, or any of its components, to meet any of the product's or component's specifications, including the extension of such investigation to other batches of the same product and other products that may have been associated with the specific failure or discrepancy; (b) take required and timely corrective actions for all products that fail to meet specifications; and (c) document in a timely manner investigations and any corrective actions and retain such documentation, as appropriate;

(6) Defendants have established and implemented container closures systems that are clean, and, where indicated by the nature of the drug, sterilized and processed to remove pyrogenic properties (depyrogenation) using a validated method to assure they are suitable for their intended use;

(7) Defendants ensure that the equipment used in the manufacture and/or holding of their drugs is appropriately designed to facilitate cleaning and maintenance and Defendants have shown through valid scientific evidence that such equipment is adequate for its intended use;

(8) Defendants ensure that their finished drug products are properly labeled and are not otherwise unapproved new drugs; and

(9) Defendants ensure that their quality control unit has the adequate responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, and labeling of drug products, and has the authority to review and fully investigate any errors that may occur;

F. The CGMP Expert certifies in writing to FDA and Defendants that:

(1) The CGMP Expert has inspected Defendants' facility, methods, and controls used to manufacture, hold, and/or distribute drugs as described in 9.E.;

(2) All deviations brought to Defendants' attention by FDA, the CGMP Expert, and any other source have been corrected; and

(3) Defendants' facility, methods, and controls comply with this Decree, the Act, and its implementing regulations, including that Defendants' facility, methods, and controls are adequate to prevent their drugs from becoming adulterated within the meaning of 21 U.S.C. §§ 351(a)(2)(A) and 351(a)(2)(B), unapproved new drugs within the meaning of 21 U.S.C. § 355, and/or misbranded within the meaning of 21 U.S.C. § 352(f)(1).

As part of this certification, Defendants shall ensure that the CGMP Expert includes a detailed and complete report of the results of the inspection(s) conducted under paragraph 9.E.;

G. Defendants report to FDA in writing the actions they have taken to:

(1) Correct all insanitary conditions and deviations from CGMP brought to Defendants' attention by FDA, the CGMP Expert, or any other source; and

(2) Ensure that Defendants' facility, methods, and controls used to manufacture, hold, and/or distribute Defendants' drugs are established, operated, and administered in conformity with the Act and its implementing regulations;

H. Defendants establish and maintain a system to report to FDA through the MedWatch reporting system adverse drug experiences (in the manner described in 21 C.F.R. § 310.305 and/or 21 C.F.R. § 314.80) associated or potentially associated with any and all of Defendants' drugs as soon as possible, but no later than fifteen (15) days after Defendants' initial receipt of reportable adverse event information;

I. Defendants establish and maintain a system to submit to FDA, at the address specified in paragraph 27, Field Alert Reports (in the manner and as described in 21 C.F.R. § 314.81(b)(1)) for all of Defendants' distributed drugs within three (3) working days after initial receipt of information triggering the Field Alert Report;

J. FDA representatives, without prior notice and when FDA deems necessary, inspect Defendants' facility to determine whether Defendants' facility, methods, and controls used to manufacture, hold, and/or distribute drugs comply with this Decree, the Act, and its implementing regulations, including whether Defendants' facility, methods, and controls are adequate to prevent their drugs from becoming adulterated within the meaning of 21 U.S.C. §§ 351(a)(2)(A) and 351(a)(2)(B) and/or misbranded within the meaning of 21 U.S.C. § 352(f)(1). FDA will begin an inspection under this paragraph as soon as practicable; and

K. FDA notifies Defendants in writing that Defendants appear to be in compliance with all of the requirements set forth in paragraphs 9.A.–9.I. of this Decree. FDA will notify Defendants as soon as practicable. In no circumstance, shall FDA's silence be construed as a substitute for written notification.

10. Notwithstanding paragraphs 9 and 14.A., after Defendants have met the reporting requirements for wholesale distributors required by 21 U.S.C. § 353(e)(2)(A), Defendants may, but only in their capacity as a wholesale distributor, receive and distribute FDA-approved drug products that are not manufactured by Defendants.

11. Within ten (10) days from the entry of this Decree, Defendants shall, under FDA's supervision, destroy all finished and in-process drugs and all components, that are in Defendants' possession, custody, or control, except for (a) finished or in-process drugs that Defendants need for their validation studies, which Defendants will not distribute, (b) unopened bulk drug substances, and (c) FDA-approved drug products received or held in connection with Defendants' wholesale distribution under paragraph 10. Defendants shall bear the costs of destruction and the costs of FDA's supervision at the rates specified in paragraph 17. Defendants shall be responsible for ensuring that the destruction is carried out in a manner that complies with all applicable federal and state environmental laws, and any other applicable federal or state laws.

12. After Defendants have complied with paragraph 9, and received written notification from FDA under paragraph 9.K., Defendant shall retain an independent person who meets the criteria described in paragraph 9.C. and who is qualified to assess Defendants' compliance with paragraph 9 (the "Auditor") to conduct audit inspections of Defendants' facility. Defendants shall notify FDA in writing as to the identity and qualifications of the Auditor as soon as they retain such Auditor. After Defendants receive written notification from FDA under paragraph 9.K., audit inspections under this paragraph shall commence no less frequently than once every four (4) months for a period of one (1) year, and once every six (6) months thereafter for an additional four (4) year period.

A. At the conclusion of each audit inspection described in this paragraph, the Auditor shall prepare a written audit report ("Audit Report") analyzing whether Defendants comply with the requirements of this Decree, the Act, and its implementing regulations. The Audit Report shall identify all deviations from this Decree, the Act, and its implementing regulations ("audit report observations"). Beginning with the second Audit Report, the Auditor shall also assess the adequacy of any corrective actions taken by Defendants to correct all previous audit report observations, and include this information in the Audit Report. The Audit Report shall be delivered contemporaneously to Defendants and FDA by courier service or overnight delivery service no later than fifteen (15) days after the date each audit inspection is completed. In addition, Defendants shall maintain all Audit Reports in a separate file at Defendants' facility to which the report pertains and shall promptly make the Audit Reports available to FDA upon request.

B. If an Audit Report contains any audit report observations, Defendants shall, within thirty (30) days after receipt of the Audit Report (or such longer period approved by FDA as described below), correct those deviations, unless FDA notifies Defendants in writing that a shorter time period is necessary. If, after receiving the Audit Report, Defendants believe that correction of the deviations will take longer than thirty (30) days, Defendants shall, within ten (10) days after receipt of the audit report, propose a schedule for completing corrections. FDA shall, as it deems appropriate, review and approve the proposed schedule in writing prior to implementation. In no circumstance shall FDA's silence be construed as a substitute for written approval. Defendants shall complete all corrections according to the approved correction schedule. Within thirty (30) days after Defendants' receipt of an Audit Report, unless FDA notifies Defendants that a shorter time period is necessary, or within the time period provided in a correction schedule approved by FDA, the Auditor shall review the actions taken by Defendants

to correct the audit report observations. Within five (5) business days after completing that review, Defendants shall ensure that the Auditor reports in writing to FDA whether each of the audit report observations has been fully corrected and, if not, which audit report observations remain uncorrected.

13. Upon receipt of written notification from FDA under paragraph 9.K., Defendants and each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them, including, but not limited to, Hauck Family Trust, who have received actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any act that:

A. Violates 21 U.S.C. § 331(a) by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce, any drug that is adulterated within the meaning of 21 U.S.C. §§ 351(a)(2)(A) or 351(a)(2)(B), or misbranded within the meaning of 21 U.S.C. § 352(f)(1);

B. Violates 21 U.S.C. § 331(k) by causing any drug to become adulterated within the meaning of 21 U.S.C. §§ 351(a)(2)(A) or 351(a)(2)(B), and misbranded within the meaning of 21 U.S.C. § 352(f)(1), while such drug is held for sale after shipment of one or more of its components in interstate commerce;

C. Violates 21 U.S.C. § 331(d) by introducing or causing to be introduced, or delivering or causing to be delivered for introduction into interstate commerce, any new drug that is neither approved under 21 U.S.C. § 355, nor exempt from approval; and/or

D. Any act that results in the failure to implement and continuously maintain the requirements of this Decree.

14. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, analyses of samples, a report or data prepared or submitted by Defendants, the CGMP Expert and/or the Auditor, or any other information, that Defendants have failed to comply with the provisions of this Decree, violated the Act and/or its implementing regulations, and/or that additional corrective actions are necessary to achieve compliance with this Decree, the Act and/or its implementing regulations, FDA may, as and when it deems necessary, notify Defendants in writing of the noncompliance and order Defendants to take appropriate corrective action, including, but not limited to, ordering Defendants to immediately take one or more of the following actions:

A. Cease all manufacturing, processing, packing, labeling, holding, and/or distribution of any and all drug(s);

B. Recall specified drugs manufactured, held, and/or distributed by Defendants. Defendants shall initiate the recall(s) within twenty-four (24) hours after receiving notice from FDA that a recall is necessary. Defendants shall, under FDA's supervision, destroy all finished and/or in-process drugs and components that are in Defendants' possession, custody, or control, for which a recall was initiated. Defendants shall bear the costs of such recall(s), including the costs of destruction and the costs of FDA's supervision at the rates specified in paragraph 17. Defendants shall be responsible for ensuring that the destruction is carried out in a manner that complies with all applicable federal and state environmental laws, and any other applicable federal or state law;

C. Submit additional reports or information to FDA;

D. Repeat, revise, modify, or expand any report(s) or plan(s) prepared pursuant to this Decree;

E. Issue a safety alert with respect to a drug manufactured, processed, packed, labeled, held, and/or distributed by Defendants; and/or

F. Take any other corrective action(s) as FDA, in its discretion, deems necessary to protect the public health or bring Defendants into compliance with this Decree, the Act and/or its implementing regulations.

This remedy shall be separate and apart from, and in addition to, any other remedy available to the United States under this Decree or under the law.

15. The following process and procedures shall apply in the event that FDA issues an order under paragraph 14.

A. Unless a different time frame is specified by FDA in its order, within ten (10) business days after receiving such order, Defendants shall notify FDA in writing either that: (1) Defendants are undertaking or have undertaken corrective action, in which event Defendants shall also describe the specific action taken or proposed to be taken and the proposed schedule for completing the action; or (2) Defendants do not agree with FDA's order. If Defendants notify FDA that they do not agree with FDA's order, Defendants shall explain in writing the basis for their disagreement; in so doing, Defendants may also propose specific alternative actions and timeframes for achieving FDA's objectives.

B. If Defendants notify FDA that they do not agree with FDA's order, FDA will review Defendants' notification, and thereafter, in writing, affirm, modify, or withdraw its order, as FDA deems appropriate. If FDA affirms or modifies its order, it will explain the basis for its decision in writing. The written notice of affirmation or modification shall constitute final agency action.

C. If FDA affirms or modifies its order, Defendants shall, upon receipt of FDA's order, immediately implement the order (as modified, if applicable), and may, if they so choose, bring the matter before this Court on an expedited basis. While seeking Court review, Defendants shall continue to diligently implement and comply with FDA's order, unless and until the Court stays, reverses, or modifies FDA's order. Any judicial review of FDA's order under this paragraph shall be made pursuant to paragraph 25.

D. The process and procedures set forth in paragraphs 15.A.– C. shall not apply to any order issued pursuant to paragraph 14 if such order states that, in FDA's judgment, the matter raises a significant public health concern. In such case, Defendants shall, upon receipt of such order, immediately and fully comply with the terms of that order. Should Defendants seek to challenge any such order, they may petition this Court for relief while they implement FDA's order. Any judicial review of FDA's order under this paragraph shall be made pursuant to paragraph 25.

Any cessation of operations or other action described in paragraph 14 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Decree, the Act, and its implementing regulations, and that Defendants may resume operations. Upon Defendants' written request to resume operations, FDA will determine whether Defendants appear to be in such compliance, and, if so, issue to Defendants a written notification permitting, as appropriate, resumption of operations. FDA will issue such written notification to Defendants as soon as practicable. In no circumstance shall FDA's silence be construed as a substitute for written notification. The costs of FDA inspections, sampling, testing, travel time, and subsistence expenses to implement the remedies set forth in this paragraph and paragraph 14

shall be borne by Defendants at the rates specified in paragraph 17. This provision shall be separate and apart from, and in addition to, all other remedies available to FDA.

16. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendants' facility, collect samples, and, without prior notice, take any other measures necessary including but not limited to, FDA's authorities set out in 21 U.S.C. § 374, for example, observing routine production to monitor and ensure continuing compliance with the terms of this Decree. During such inspections, FDA representatives shall be permitted access to Defendants' facility including, but not limited to, all buildings, equipment, in-process or unfinished and finished materials and products, containers, labeling, and other promotional material therein; to take photographs and make video recordings; to take samples, without charge to FDA, of finished and unfinished materials and products, containers and packaging material therein, labeling, and other promotional material; and to examine and copy all records relating to the receipt, manufacturing, holding, and/or distribution of any and all drugs and their components. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to conduct inspections under the Act, 21 U.S.C. § 374.

17. Defendants shall pay all costs of FDA's supervision, inspections, investigations, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with this Decree, including the travel incurred by specialized investigatory and expert personnel, at the standard rates prevailing at the time the costs are incurred. As of the date that this Decree is signed by the parties, these rates are: $95.39 per hour and fraction thereof per representative for inspection work; $114.33 per hour or fraction thereof per representative for

analytical or review work; $0.545 per mile for travel by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per representative and per day for subsistence expenses, where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

18. Within three (3) days after becoming aware of any of the following information about any drugs manufactured, held, and/or distributed at or from Defendants' facility, Defendants shall submit to FDA at the address specified in paragraph 27, a product quality report describing all information pertaining to any:

A. Product and/or manufacturing defects that could result in serious adverse drug experiences;

B. Mislabeling or mix-ups, including incident(s) that causes any drug or its labeling to be mistaken for, or applied to, another article; and/or

C. Contamination, including any bacteriological, fungal, or environmental contamination, or any significant chemical, physical, or other change or deterioration, or lack of stability or incorrect potency, in any drug.

19. Within seven (7) days after entry of this Decree, Defendants shall post a copy of this Decree on a bulletin board in the employee common areas at Defendants' facility, and, if applicable, publish the Decree on any internal and/or publically-available website maintained and/or controlled by Defendants. Defendants shall ensure that the Decree remains posted as described herein for as long as the Decree remains in effect.

20. Within seven (7) days after entry of this Decree, Defendants shall provide a copy of this Decree, by personal service or certified mail (restricted delivery, return receipt requested), to each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (collectively referred to as "Associated Persons"). Within thirty (30) days after entry of this Decree, Defendants shall provide to FDA an affidavit of compliance, signed by a person with personal knowledge of the facts, stating the fact and manner of compliance with the provisions of this paragraph and identifying the names, addresses, and positions of all persons who have received a copy of this Decree pursuant to this paragraph, and attaching a copy of the executed certified mail return receipts. Within seven (7) days after receiving a request from FDA for any information or documentation that FDA deems necessary to evaluate Defendants' compliance with this paragraph, Defendants shall provide such information or documentation to FDA.

21. Within seven (7) days after entry of this Decree, Defendants shall hold a general meeting or series of smaller meetings for all Associated Persons, at which they shall describe the terms and obligations of this Decree. Such meeting or meetings may occur via teleconference. Within fifteen (15) days after entry of this Decree, Defendants shall provide to FDA an affidavit of compliance, signed by a person with personal knowledge of the facts, stating the fact and manner of compliance with the provisions of this paragraph and a copy of the agenda, list of attendees, and meeting minutes from the meeting(s) held pursuant to this paragraph.

22. In the event that Defendants becomes associated with any additional Associated Person(s) at any time after entry of this Decree, Defendants immediately shall provide a copy of this Decree, by personal service or certified mail (restricted delivery, return receipt requested), to such Associated Person(s). Within thirty (30) days after each time Defendant becomes associated

with any such additional Associated Person(s), Defendants shall provide to FDA an affidavit stating the fact and manner of their compliance with this paragraph, identifying the names, addresses, and positions of all Associated Persons who received a copy of this Decree pursuant to this paragraph, and attaching a copy of the executed certified mail return receipts. Within seven (7) days after receiving a request from FDA for any information or documentation that FDA deems necessary to evaluate Defendants' compliance with this paragraph, Defendants shall provide such information or documentation to FDA.

23. Defendants shall notify FDA at least fifteen (15) days before any change in ownership, character, or name of any of Defendants' businesses, including incorporation, reorganization, relocation, bankruptcy, dissolution, assignment, or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, or any other change in the corporate structure, or identity of Delta Pharma, or in the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect obligations arising out of this Decree. Defendants shall provide a copy of this Decree to any potential successor or assign at least fifteen (15) days before any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) days prior to any such assignment or change in ownership.

24. If any Defendant fails to comply with any provision of this Decree, the Act and/or its implementing regulations, including any time frame imposed by this Decree, then Defendants shall pay to the United States of America: five thousand dollars ($5,000) in liquidated damages for each day such violation continues; an additional sum of five thousand dollars ($5,000) in liquidated damages for each violation; and further additional sum equal to the retail value of drug products that have been manufactured, held, and/or distributed in violation of this Decree, the Act,

and/or its implementing regulations. The remedy in this paragraph shall be in addition to any other remedies available to the United States under this Decree or the law.

25. Defendants shall abide by the decisions of FDA, and FDA's decisions shall be final. All decisions conferred upon FDA in this Decree shall be vested in FDA's discretion and, to the extent that these decisions are subject to review, shall be reviewed by this Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Decree shall be based exclusively on the written record before FDA at the time of the decision. No discovery shall be taken by either party.

26. Should the United States of America bring, and prevail in, a contempt action to enforce the terms of this Decree, Defendants shall, in addition to other remedies, pay all attorneys' fees and costs, travel expenses incurred by attorneys and witnesses, expert witness fees, investigational and analytical expenses, court costs, and any other costs or fees incurred by the United States in bringing such an action.

27. All notifications, certifications, reports, correspondence, and other communications to FDA required by the terms of this Decree shall be prominently marked "Consent Decree Correspondence," and shall be addressed to the Director, FDA, ORA/OPQO - Pharm 2 District Office, 4040 N. Central Expressway, Dallas, TX 75204.

28. No sooner than sixty (60) months after entry of this Decree, Defendants may petition FDA for leave to ask this Court for relief from this Decree. If, at the time of the petition, in FDA's judgment, Defendants have maintained a state of continuous compliance with this Decree, the Act, and its implementing regulations for at least sixty (60) months, the United States will not oppose the petition, and Defendants may request the Court to grant such relief.

29. This Court retains jurisdiction of this action and the parties thereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

IT IS SO ORDERED, this 8th day of June, 2018.

Neal Biggers
UNITED STATES DISTRICT JUDGE

The undersigned hereby consent to the entry of the foregoing Decree.

For Defendants:

TOMMY T. SIMPSON
Individually and on behalf of DELTA PHARMA, INC.

CHARLES MICHAEL HARRISON
Individually

DANIEL G. JARCHO
Attorney for Defendants

CATHY L. BURGESS
Attorney for Defendants

For the United States of America:

WILLIAM C. LAMAR
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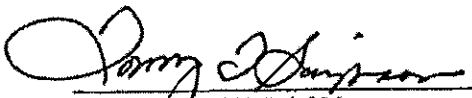
For Defendants:



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